A8 cont'd

41. (Amended) The method of claim 40 further comprising selecting the transformed plant tissue on a growth medium comprising a selective agent.

A9

42. (New) The method of claim 7 wherein the carbon source is maltose or sucrose.

REMARKS

Reconsideration is respectfully requested. Claims 1, 4-8, 13, 25, 32, 35 and 40-41 have been amended. Claim 9 has been cancelled. New claim 42 has been added. After entry of this amendment claims 1-8 and 10-42 will be pending.

Related Applications

The status of cited applications has been updated to conform with the Examiner's request.

Drawings

The applicant thanks the examiner for approving the submitted drawings.

CLAIM REJECTIONS – 35 U.S.C. § 112

The Examiner has rejected claims 1-41 under 35 U.S.C. § 112, second paragraph as allegedly being indefinite for failing to particularly point out and claim the subject matter with the applicants regard as the invention.

Claim 1

The Examiner suggests that the phrase "a cell of green regenerative tissue" be amended to "a plant cell." For purposes of clarity, in claim 1, the phrase has been amended to "a plant cell of green regenerative tissue."

The Examiner also states that the phrase "dim light" in claim 1 is unclear because the term lacks a comparative basis. "Dim light" is defined several times in the specification as being light of approximately 10 to 30 μE. See for example p. 9 at line 9, p. 77 at line 5, and p. 88 at line 30. For the purpose of clarity, but without prejudice or disclaimer, "dim light" has been amended to state dim light of "approximately 10 to 30 μE."

The Examiner has also suggested that "intermediate" be deleted from "intermediate-incubation medium" in Claim 1 because a first and final incubation medium are not defined. In accordance with the Examiner's request, Claim 1 and its dependent claims have been so amended.

Claim 4

The Examiner asserts that claim 4 appears to exclude the cytokinin of claim 1. Claim 4 has been amended to delete the expression "the intermediate-incubation medium comprises" as the Examiner suggested.

Claim 5

The Examiner asserts that claim 5 appears to exclude the auxin of claim 1. Claim 5 has been amended to delete the expression "the intermediate-incubation medium comprises" as the Examiner suggested.

Claim 6

Since there is no longer antecedent basis for "intermediate" in claim 1, "intermediate" has been deleted from "intermediate-incubation medium" in claim 6.

Claim 7

Since there is no longer antecedent basis for "intermediate" in claim 1, "intermediate" has been deleted from "intermediate-incubation medium" in claim 7.

Claim 8

The expression "further comprises" has been deleted from claim 8 as the Examiner suggested.

Claim 9

The Examiner states that claim 9 does not further limit claim 1. Claim 9 has been cancelled.

Claim 25

The Examiner has states that claim 25 implies that the starting material is not "green regenerative tissue." This assertion by the Examiner is correct. Claim 25 is directed to a method of ***producing*** green regenerative tissue, which can then be used in other regenerative processes. For example, green regenerative tissue produced by the method of claim 25 can then be used as the starting material for the method claimed in claim 1. The term "dim light" in claim 25 has also been amended to further state that the light is " approximately 10 to 30 μE " for purposes of clarity and consistency.

Claim 32

Claim 32 has been amended to recite "A method of producing the callus of claim 29" as the Examiner has suggested.

The Examiner has also stated that "excising the root and shoot from the seed" in claim 32 is unclear for failing to distinguish between "seed" and "germinating seed," and for failing to indicate whether or not the excised root and shoot have been discarded or retained. Claim 32 has been amended to recite "excising and discarding the root and shoot from the germinating seed to produce a remaining portion of the germinating seed" to make it clear that the root and shoot are discarded as indicated at page 3, lines 24-27 of the application as filed.

The Examiner has also stated that claim 32 is incomplete for failing to result in a callus. Claim 32 has also been amended to read "to produce callus" and is now complete.

OK

Claim 35

The Examiner has stated that claim 35 does not use "green regenerative tissue" as the starting plant tissue. The Examiner is correct that claim 35 does not use "green regenerative tissue" as the starting plant tissue. Instead, claim 35 is directed to a method for regenerating a plant from plant tissue by incubating plant tissue to *produce* "green regenerative tissue". OK

Claims 40-41

The Examiner has asserted that it is unclear how the steps set forth in claims 40-41 apply to claim 35. Claims 40-41 relate to claim 35 in that they further include introducing a nucleic acid into at least one cell of the green regenerative tissue of claim 35 to produce transformed tissue (claim 40) and selecting the transformed tissue (claim 41.) As such, claims 40-41 are clear.

prob OK

In light of the above, applicants assert that the pending claims meet the requirements of 35 U.S.C. § 112, second paragraph.

CLAIM REJECTIONS – 35 U.S.C. § 102 (b)

The Examiner's Rejections

Wan, et al.

The Examiner has rejected claims 1-16, 25-27, 29-31, 33-37 and 39-41 under 35 U.S.C. § 102 (b) as being anticipated by Wan, Y and Lamaux, PG (Plant Physiol 104:37-48(1994)).

As a preliminary matter, the Examiner has asserted that since "dim light" is not defined adequately in the specification, the Office interprets dim light as being any light conditions. The term "dim light" is defined in the specification numerous times as light of approximately 10 to 30 μE. See for example, p. 9 at line 9, p. 77 at line 5, and p. 88 at line 30. Additionally, claims 1, 25, 32, and 35 have been amended such that the term "dim light" is further clarified as "approximately 10 to 30 μE." As such, "dim light" is not any light but is light of approximately 10 to 30 μE.

The Examiner also states that the Office interprets callus as being "green regenerative tissue." As defined in the Specification, "Callus" refers to undifferentiated plant tissue. Callus may or may not be green regenerative tissue, and may appear in several other colors. (Specification, p. 17 at line 29, for example.) The specification states on p. 2, line 29 – p. 3, line 1 that "green regenerative tissue may also be referred to as green callus tissue." However, *non-green* callus is not a regenerative tissue. The specification states on p. 3 that "one aspect of the invention encompasses methods for preparing green regenerative tissues by incubating plant tissue under dim light for sufficient time to produce green regenerative tissue." The specification then states that generally the plant tissue, (that is the starting material), will be callus tissue. Thus the specification teaches that green regenerative tissue will be *produced* from callus. (Specification, p. 3.) Thus "callus" should be interpreted differently than "green regenerative tissue." The specification then defines dim light as being that of approximately 10 to 30 μE. See for example, p. 9 at line 9, p. 77 at line 5, and p. 88 at line 30.

Turning now to the rejection of the claims under 35 U.S.C. § 102 (b), this statute denies a patent if "the invention was patented or described in a printed publication in this or in a foreign

country or in public use or one sale in this country, more than one year prior to the date of application for patent in the United States." For a 102(b) bar to operate, each and every element of the claimed invention must be present in the printed publication.

The Examiner has asserted that Wan teaches a method for producing a transformed Golden Promise barley plant (title and abstract, p.37; p. 38 1st column 2nd paragraph) by introducing a nucleic acid into a cell of callus derived from an immature zygotic embryo (p. 37 2nd column, 2nd paragraph) to produce a transformed plant cell, culturing the transformed plant cell under conditions comprising dim light (p.38, column one, 2nd paragraph.)

Applicants respectfully assert that the Examiner has mischaracterized the teachings of Wan on several grounds. In contrast to the Examiner's statement, the only teaching in Wan regarding dim light refers to the growth of Igri **seedlings** under dim (10 – 15 μE) light. (p. 38, column one, 2nd paragraph). Igri is a winter cultivar of barley, distinct from Golden Promise, a spring cultivar (p. 38, column one, 2nd paragraph).

Secondly, the Examiner also stated that Wan teaches the use of dim light for culturing the transformed plant cell (p. 38, column one, 2nd paragraph). Applicants respectfully assert that Wan teaches the culturing under dim light of ***seedlings***, which are grown in soil, not the transformed plant cell. Applicants also assert that the use of dim light in Wan is for the purpose of *vernalization* of Igri seedlings, not the culturing of transformed plant cells.

The Examiner also has stated that the use of dim light in Wan is for the culturing of transformed plant cells in on an intermediate-incubation medium. Wan teaches the use of dim light on seedlings grown *in soil*, not the culturing of transformed plant cells on a medium. (p. 38, column one, 2nd paragraph) as the Examiner has characterized.

Wan teaches the production of callus from Golden Harvest barley by harvesting immature embryos (IE) from spikes of Golden Harvest and the culturing of these embryos on callus induction medium (CIM) in the dark. (p. 38, 1st column, 2nd paragraph.) Wan also teaches the production of callus from Igri barley. Wan teaches the growth of Igri seedlings (plants) under dim light (p. 38, 1st column, 2nd paragraph) and then the harvesting and culturing of

anthers from these plants in regenerative medium to produce microspore-derived embryos (MDE). (p. 38, 1st column, 4th paragraph.) Wan teaches the transformation of callus or MDEs by microprojectile bombardment and then the culturing of the resulting transformed cells in callus induction medium. (p. 38, 2nd column, 3rd paragraph.)

Applicants respectfully assert that the pending claims clearly distinguish Wan.

Claims 1-24 recite the culturing of transformed plant cells under dim light of approximately 10 to 30 μE. In contrast, Wan teaches the culturing of transformed plant cells under normal light conditions.

Claims 25-34 recite the creation of green regenerative tissue by the incubation of plant tissue on a growth medium under light of approximately 10 to 30 μE . Wan teaches the creation of callus by incubation of plant tissue in the dark, followed by transfer to normal light. (p. 38, 1st column, 3rd and 4th paragraphs.) Wan also does not mention green regenerative tissue.

Claims 35-42 recite the regeneration of a plant from plant tissue by the incubation of plant tissue on a growth medium under light of approximately 10 to 30 μE. Wan teaches the regeneration of a plant from plant tissue under fluorescent light at 45 to 55 μE. (p. 39, 1st column, 4th paragraph.)

In light of the above, applicants respectfully assert that Wan does not anticipate the claimed invention.

Vasil

The Examiner has rejected claims 1-11, 14, 15, 17, and 25-41 under 35 U.S.C. § 102 (b) as being anticipated by Vasil. Vasil teaches a method for producing a transformed wheat plant by bombarding a nucleic acid into a cell of Type C callus (column 5, line 47). Vasil teaches the production of a Type C callus by successive subcultures of callus tissue to for 5 months to produce "aged callus" (column 6, lines 39 – 40). Vasil teaches the maintenance of embyrogenic callus in total darkness to produce "Type C callus" (column 8, line 42).

Vasil does not teach the use of dim light of approximately 10 to 30 μE for culturing a transformed plant cell. Vasil also does not teach the use of dim light of approximately 10 to 30 μE to prepare green regenerative tissue from plant tissue. Vasil does not teach the induction of callus by germinating seeds under dim light of approximately 10 to 30 μE.

The Examiner also asserts that Vasil teaches the transformation of Anza wheat. Vasil does not report the successful production of transgenic Anza wheat. Vasil mentions Anza wheat, but only reports the transformation of Pavon wheat (Column 7 at line 23, Table 1).

In light of the above, applicants respectfully assert that Vasil does not anticipate the claimed invention.

CLAIM REJECTIONS – 35 U.S.C. § 103

The Examiner has rejected claims 1 – 41 under 35 U.S.C. 103 as being unpatentable over Wan, Y and Lemaux, PG (Plant Physiol 104: 37-48 (1994)) and Vasil USP 5,405,765.

35 USC 103(a) states "a patent may not be obtained thought the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to person having ordinary skill in the art to which said subject matter pertains.

The Examiner has stated that since claims 1-17 and 25-41 have been rejected under 35 U.S.C. § 102, claims 18-24 would be obvious to one of ordinary skill in the art since they recite the transformation and regeneration of commercially available monocot cultivars.

Prima facie case

The Examiner fails to establish a prima facie case for obviousness. Specifically none of the cited references teach or suggest all of the claim limitations; 2) the prior art combined with

general knowledge fails to include a suggestion or incentive to modify the references; and 3) the references fail to teach that a modification would have a reasonable chance of success.

The teachings of Wan and Vasil have been discussed above.

Claims 18-24 depend on claim 1. Claim 1 recites "culturing the transformed plant cell under conditions of approximately 10 to 30 μE light." As discussed above, neither Wan or Vasil alone or in combination teach one to culture callus, green regenerative tissue, or transformed plant cells under light of approximately 10 to 30 μE.

Neither reference contains a suggestion to try other conditions including different light levels, or to combine their teachings with other references which might teach other light levels.

In addition, both Wan and Vasil teach away from the claimed invention. Wan teaches the culturing of plant tissue under conditions of unspecified light, or in complete darkness. (p. 38, 1st column, 3rd and 4th paragraphs.) Vasil also teaches away from the claimed invention by culturing callus and embyrogenic plant tissue under complete darkness, followed by regeneration under a standard 16-hour light cycle. (Column 8, lines 10-12 and lines 35-36). In contrast, the current invention teaches one to culture callus, green regenerative tissue, or transformed plant cells under light of approximately 10 to 30 μE. Additionally, there is no reference which suggests that use of dim light of approximately 10 to 30 μE during plant cell culturing was within the knowledge of the ordinary skilled worker at the time.

The Examiner has asserted that it would be well within the mean of one of ordinary skill in the art at the time the invention was made to use the teachings of Wan and Vasil to transform and regenerate these commercially valuable cultivars with a reasonable expectation of success. Applicants respectfully assert that since the limitations of claims 1-17 and 25 –41 are not taught by the references, it would not be obvious to combine those methods with the use of the commercially available monocot cultivars of claims 18 –24.

Even if the Examiner established a prima facie case of obviousness, applicants assert that secondary factors described in the specification rebut any prima facie case of obviousness. These secondary factors include long-felt need, failure of others, and unexpected results.

Genetic improvement of commercial crop cultivars has been hampered for a significant time because techniques for *in vitro* culture, transformation, and regeneration have been less effective with these commercially important cultivars. (Specification, p. 1)

Wan reported repeated failure to produce green plants, resulting in a high incidence of albinism in barley plants transformed by its methods. Albinism is a common problem in barley tissue culture. (Wan, p. 47, 1st column 2nd full paragraph) Wan speculated that numerous factors such as the "state of the donor plant" or "some unknown factor" might be the cause of the albinism in plants transformed by its methods. (Wan, p. 47, 1st column 2nd full paragraph.) However, neither Wan nor Vasil suggested or speculated that the use of dim light of approximately 10 to 30 μE would reduce the incidence of albinism in cultured barley plant cells. In contrast, the current application, using light of approximately 10 to 30 μE, reports a success rate of 100% of generation of green barley plants after transformation. (Specification, table 6) to satisfy the long felt need and provide a solution for the failure of others.

Unexpected results in the application also include the successful production of transformed Anza wheat lines at a rate of 4.9%. (Specification, Table 12). Anza wheat has previously been recalcitrant to transformation (Specification, p. 66, line 18). These results and others rebut a prima facie case of obviousness, even if the Examiner were to find one.

The prior art therefor fails to render the pending claims obvious. In view of the above, Applicants respectfully request that rejections under 35 USC § 103 be withdrawn.

DOUBLE PATENTING REJECTIONS

The Examiner has rejected claims 1-41 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of USP 6,235,529. A terminal disclaimer in compliance with 37 CFR 1.321(c) is filed herewith to overcome this rejection.

Conclusions

In light of the above, applicants submit that the pending claims are in condition for allowance. Should there be any remaining issues that remain unresolved, the Examiner is encouraged to contact the undersigned by telephone.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Version with markings to show changes made**".

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. **416272002220**. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Dated: September 5, 2002

By: 

Michael R. Ward
Registration No. (38,651)

Morrison & Foerster LLP
425 Market Street
San Francisco, California 94105-2482
Telephone: (415) 268-6237
Facsimile: (415) 268-7522

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification

Please replace the paragraph on p. 1 entitled CROSS REFERENCE TO RELATED APPLICATIONS with the following new paragraph:

--This application is a continuation-in-part of U.S. Application Serial No. 08/845,939 filed on April 29, 1997, now issued as U.S. Patent No. 6,235,529, which is hereby incorporated herein in its entirety by reference.--

In the Claims

1. (Amended) A method for producing a transformed plant, comprising the steps of: introducing a nucleic acid into a plant cell of green regenerative tissue to produce a transformed plant cell;

culturing the transformed plant cell under [conditions comprising] dim light of approximately 10 to 30 μE on an [intermediate-]incubation medium comprising an auxin and a cytokinin, thereby promoting proliferation and formation of a transformed structure that is competent to regenerate; and

culturing the transformed structure on a regeneration medium to produce the transformed plant.

4. (Amended) The method of claim 1 wherein [the intermediate-incubation medium comprises] the auxin is at a concentration of about 0.1 mg/L to about 5 mg/L.

5. (Amended) The method of claim 1 wherein [the intermediate-incubation medium comprises] the cytokinin is at a concentration of about 0.01 mg/L to about 5 mg/L.

6. (Amended) The method of claim 1 wherein the [intermediate-]incubation medium further comprises copper at a concentration of about 0.1 μM to about 50 μM.

7. (Amended) The method of claim 1 wherein the [intermediate-]incubation medium further comprises a carbon source [comprising maltose or sucrose].

8. (Amended) The method of claim 1, wherein [the intermediate-incubation medium: comprises] the auxin is at a concentration of about 0. 1 mg/L to about 5 mg/L and the cytokinin is at a concentration of about 0. 1 mg/L to about 5 mg/L; and the incubation medium further comprises [maltose, and] copper at a concentration of about 0. 1 μM to about 50 μM, and maltose.

13. (Amended) The method of claim 12 wherein bombardment is performed at about 900 to about 1100 [about] psi.

25. (Amended) A method of preparing green regenerative tissue from a plant comprising incubating plant tissue on a growth medium under [conditions comprising] dim light of approximately 10 to 30 μE for a sufficient time to produce green regenerative tissue, wherein the growth medium comprises auxin at a concentration of about 0. 1 mg/L to about 5 mg/L, cytokinin at a concentration of from 0.00 mg/L to about 2 mg/L, copper at a concentration of about 0. 1 μM to about 50 μM, and a carbon source.

32. (Amended) [The method of claim 29 wherein the callus is produced by a method] A method of producing the callus of claim 29 comprising the steps of:

germinating a seed on a callus-induction medium comprising auxin at a concentration of about 0. 1 mg/L to about 5 mg/L, cytokinin at a concentration of from 0.0 mg/L to about 2 mg/L, copper at a concentration of about 0.1 μM to about 50 μM, and a carbon source, thereby allowing root and shoot formation;

excising and discarding the root and shoot from the germinating seed to produce a remaining portion of the germinating seed;

incubating the remaining portion of the germinating seed under [conditions comprising] dim light of approximately 10 to 30 μE; and selecting nodular, compact structures that form on the remaining portion of the germinating seed to produce callus.

35. (Amended) A method for regenerating a plant from plant tissue, comprising: incubating plant tissue on a growth medium under [conditions, comprising] dim light of approximately 10 to 30 μE for a sufficient time to produce green regenerative tissue, wherein the growth medium comprises auxin at a concentration of about 0. 1 mg/L to about 5 mg/L, cytokinin at a concentration of from 0.0 mg/L to about 2 mg/L, copper at a concentration of about 0.1 μM to about 50 μM and a carbon source; and

transferring the regenerative tissue to a regeneration medium and

incubating the tissue so as to produce a plant.

40. (Amended) The method of claim 35 further comprising introducing a nucleic acid into at least one cell of the green regenerative tissue to produced transformed tissue.

41. (Amended) The method of claim 40 further comprising selecting the transformed plant tissue [comprising incubating the green regenerative tissue] on a growth medium comprising a selective agent.

42. (New) The method of claim 7 wherein the carbon source is maltose or sucrose.